IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SENJU PHARMACEUTICAL CO., LTD. KYORIN PHARMACEUTICAL CO., LTD. ALLERGAN, INC. Plaintiffs, v. APOTEX, INC. and APOTEX CORP. Defendants.	)))))))))))	Civil Action No. 12-cv-159-SLR

DEFENDANTS' AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Apotex, Inc. and Apotex Corp. (collectively "Apotex") for their Amended Answer, Affirmative Defenses and Counterclaims to Plaintiffs' Senju Pharmaceutical Co., Ltd., Kyorin Pharmaceutical Co., Ltd., and Allergan, Inc. (collectively "Plaintiffs" or "Senju") Complaint state as follows:

Nature of the Action

1. This is an action for infringement of United States Patent No. 6,333,045 ("the '045 Patent"), the claims set forth on the '045 Patent reexamination certificate, and United States Patent No. 5,880,283 ("the '283 Patent") under 35 U.S.C. §271(e)(2).

ANSWER: Defendants admit that this action purports to be one for infringement of United States Patent Nos. 6,333,045 ("the '045 patent"), including the claims set forth in the '045 patent reexamination certificate, and 5,880,283 (the '283 patent").

The Parties

2. Plaintiff Senju is a corporation organized under the laws of Japan having a place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

ANSWER: Admitted upon information and belief.

3. Plaintiff Kyorin is a corporation organized under the laws of Japan having a place of business at 5, Kanda Surugadai 2-chome, Chiyoda-ku, Tokyo 101-8311 Japan.

ANSWER: Admitted upon information and belief.

4. Plaintiff Allergan is a Delaware corporation having a place of business at 2525 Dupont Drive, Irvine, California, 92612.

ANSWER: Admitted upon information and belief.

5. On information and belief, defendant Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326.

ANSWER: Admitted.

6. On information and belief, defendant Apotex Corp. offers for sale and sells numerous generic drugs manufactured and supplied by Apotex, Inc. throughout the United States, including this judicial district.

ANSWER: Apotex admits that Apotex Corp. offers for sale and sells drug products in the United States, including this judicial district, manufactured and supplied by Apotex, Inc. All other allegations of paragraph 6 are denied.

7. On information and belief, defendant Apotex, Inc. is a corporation organized under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

ANSWER: Admitted.

8. On information and belief, defendant Apotex, Inc. manufactures numerous generic

drugs for sale and use throughout the United States, including this judicial district.

ANSWER: Apotex admits that Apotex, Inc. manufactures numerous drug products for sale and use in the United States including this judicial district, but denies all other allegations set forth in paragraph 8.

9. On information and belief, Apotex, Inc. is formulating and/or plans to formulate gatifloxacin ophthalmic solution to be marketed and sold in the United States by Apotex Corp. Plaintiffs reserve the right to amend the complaint to substitute a different party for Apotex Inc. and/or Apotex Corp. if, through discovery, Plaintiffs discover that a company other than Apotex, Inc. and/or Apotex Corp. is formulating and/or marketing and/or selling gatifloxacin ophthalmic solution.

ANSWER: Apotex denies the allegations set forth in paragraph 9. Additionally, Plaintiffs attempt to reserve rights to amend its complaint in paragraph 9 is futile, amendment of the complaint is governed by the Federal Rules of Civil Procedure, the Local Rules of this Court and any scheduling order that this Court enters in this case.

10. On information and belief, the acts of Apotex Corp. complained of herein were done with the authorization of, with the cooperation, participation, and assistance of, and in part, for the benefit of Apotex, Inc.

ANSWER: The averments of paragraph 10 are sufficiently vague and ambiguous that Apotex denies information or knowledge sufficient to form a belief as to those averments and therefore denies and demands strict proof thereof.

Jurisdiction and Venue

11. This action arises under 35 U.S.C. Section 1, *et seq.* This court has subject

matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Admitted.

12. This Court has personal jurisdiction over Apotex because of its continuous and systematic contacts with Delaware. On information and belief, Apotex directly or indirectly purposefully sells, markets, distributes, and manufactures, goods for sale in the United States and Delaware; derives substantial revenue from things used or consumed in Delaware, regularly does and solicits business in Delaware; has filed counterclaims in this Court in other actions purposefully availing itself of the rights and benefits of this Court; and has admitted and/or consented to jurisdiction in this Court on numerous occasions, including with respect to another litigation involving gatifloxacin ophthalmic solutions versus the same Plaintiffs, *e.g., Senju Pharmaceuticals Co., Ltd et al. v. Apotex Inc. et al.,* 07-779 (D. Del.).

ANSWER: Apotex admits that Apotex Corp. and Apotex, Inc. consent to jurisdiction in this Court for this action. Apotex further admits that it has consented to the jurisdiction in this Court in another litigation involving gatifloxacin ophthalmic solutions versus the same Plaintiffs, *e.g., Senju Pharmaceuticals Co., Ltd et al. v. Apotex Inc. et al.,* 07-779 (D. Del.). Apotex denies the remaining allegations set forth in paragraph 12.

13. Venue is proper in this court under 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Admitted.

Background

14. The ‘045 Patent, entitled "Aqueous Liquid Pharmaceutical Composition Comprised of Gatifloxacin," issued on December 25, 2001. A copy of the ‘045 Patent, reexamination certificate, and certificate of correction is attached to this complaint as

Exhibit A.

ANSWER: Apotex admits that what purports to be a copy of the '045 patent is attached to the Complaint as Exhibit A, which is entitled "Aqueous Liquid Pharmaceutical Composition Comprised of Gatifloxacin" and lists an issue date of December 25, 2001. Apotex denies any remaining allegations contained in paragraph 14.

15. Senju and Kyorin jointly own the entire right and interest in the '045 Patent.

ANSWER: Apotex denies knowledge or information sufficient to form a belief as to the averments of paragraph 15 and therefore denies them.

16. Allergan is the exclusive licensee of the '045 Patent for ophthalmic uses.

ANSWER: Apotex denies knowledge or information sufficient to form a belief as to the averments of paragraph 16 and therefore denies them.

17. The '283 Patent, entitled "8-Alkoxyquinolonecarboxylic Acid Hydrate With Excellent Stability And Process For Producing The Same," issued on March 9, 1999. Claim 1 of the '283 Patent claims gatifloxacin sesquihydrate. A copy of the '283 Patent is attached to this complaint as Exhibit B.

ANSWER: Apotex admits that what purports to be a copy of the '283 patent is attached to the Complaint as Exhibit B, which is entitled "8-Alkoxyquinolonecarboxylic Acid Hydrate With Excellent Stability And Process For Producing The Same," and lists an issue date of March 9, 1999. Apotex denies any remaining allegations contained in paragraph 17.

18. Kyorin owns the entire right and interest in the '283 Patent.

ANSWER: Apotex denies knowledge or information sufficient to form a belief as to the averments of paragraph 18 and therefore denies them.

19. Allergan is the exclusive licensee of the '283 Patent for ophthalmic uses.

ANSWER: Apotex denies knowledge or information sufficient to form a belief as to the averments of paragraph 19 and therefore denies them.

20. Each claim of the '045 Patent, the '045 Patent reexamination certificate, and the '283 Patent has a statutory presumption of validity that exists at all stages of a proceeding.

ANSWER: The allegations of paragraph 20 are conclusions of law to which no response or pleading is required, and therefore they are denied.

21. The '045 Patent was previously asserted by Plaintiffs against Apotex Inc. and Apotex Corp. in *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.,* 07-779 (D. Del.).

ANSWER: Admitted.

22. On June 21, 2010, the United States District Court for the District of Delaware entered judgment that Claims 1-3 and 6-9 of the '045 Patent were invalid as obvious.

ANSWER: Admitted.

23. On November 3, 2010, the United States District Court for the District of Delaware reopened the record to take additional testimony with respect to claim 7 of the '045 Patent.

ANSWER: Apotex admits that in an Order dated November 3, 2010, the United States District Court for the District of Delaware opened the record of Case No. 07-779-SLR for the parties to present additional evidence on the narrow issue of "the relationship between precipitation and solubility." Apotex denies all remaining allegations contained in paragraph 23.

24. On December 20, 2011, the United States District Court for the District of Delaware entered judgment that Claim 7 of the '045 patent was invalid as obvious.

ANSWER: Admitted.

25. Plaintiffs are appealing the district court's judgment with respect to Claim 7 of the '045 Patent from the United States District Court for the District of Delaware to the United States Court of Appeals for the Federal Circuit.

ANSWER: Apotex admits that on January 18, 2012, Plaintiffs filed a Notice of Appeal to the Federal Circuit appealing the district court's judgment with respect to Claim 7 of the '045 Patent from the United States District Court for the District of Delaware. Apotex denies knowledge or information sufficient to form a belief as to the remaining averments of paragraph 25 and therefore denies them.

26. On February 25, 2011, Senju and Kyorin filed a request for reexamination of Claims 1-3, 6, 8 and 9 of the '045 Patent with the United States Patent and Trademark Office. Plaintiffs did not request reexamination of Claims 4, 5 and 7. The request was granted on April 28, 2011, and assigned Reexamination Application Control No. 90/011509.

ANSWER: Admitted on information and belief.

27. During the prosecution of Reexamination Application Control No. 90/011509, Plaintiffs submitted, for consideration by the United States Patent and Trademark Office, the prior art, other evidence, and arguments relied upon by the Court and Apotex Inc. and Apotex Corp. in *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.,* 07-779 (D. Del.) and the Court's decision in that case. Plaintiffs further canceled claims 1-3 and 8-11, amended claim 6 and added claims 12-16.

ANSWER: Apotex admits that Plaintiffs canceled claims 1-3 and 8-11 of the '045 patent during the prosecution of Reexamination Application Control No. 90/011509. Apotex

further admits that Plaintiffs amended claim 6 and added claim 12-16 of the '045 patent during the prosecution of Reexamination Application Control No. 90/011509. Apotex denies the remaining averments set forth in paragraph 27.

28. On October 25, 2011, the United States Patent and Trademark Office issued a reexamination certificate for the '045 Patent, canceling claims 1-3 and 8-11, and issuing amended claim 6 and new claims 12-16 as patentable over the opinion, prior art, other evidence, and arguments from *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.). The United States Patent and Trademark Office informed Plaintiffs of the publication of the '045 patent reexamination certificate on October 27, 2011.

ANSWER: Apotex admits that on October 25, 2011, the United States Patent and Trademark Office issued a reexamination certificate for the '045 Patent, canceling claims 1-3 and 8-11, and issuing amended claim 6 and new claims 12-16. Apotex denies that amended claim 6 and new claims 12-16 are as patentable over the opinion, prior art, other evidence, and arguments from *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.) or that the United States Patent Office was supplied with the complete prior art, evidence and arguments from said action. Apotex denies knowledge or information sufficient to form a belief as to the remaining averments of paragraph 28 and therefore denies them.

29. Allergan is the holder of approved New Drug Application ("NDA") No. 22-548 that covers Zymaxid®, a 0.5% ophthalmic solution of gatifloxacin.

ANSWER: Admitted on information and belief.

30. In conjunction with NDA No. 22-548, Allergan has listed the '045 Patent, the '283 patent and other patents in the "Approved Drug Products with Therapeutic Equivalence

Evaluations" (the "Orange Book") maintained by the U.S. Food and Drug and Administration ("FDA"). Allergan also informed FDA of the issuance of the '045 Patent reexamination certificate. Listing patents in the Orange Book obligates drug companies seeking approval to market a generic version of listed drug before the expiration of a listed patent to provide notice to the owner of the listed patent(s) and to the NDA holder with certain exceptions which do not apply to this case.

ANSWER: Apotex admits that the FDA lists Allergan as the holder of approved New Drug Application ("NDA") No. 22-548 on its website. Apotex further admits on information and belief that Allergan has listed the '045 and '283 patents in the Orange Book. Apotex denies knowledge or information sufficient to form a belief as to the remaining averments of paragraph 30 and therefore denies them.

31. On information and belief, Apotex filed ANDA No. 203523 for gatifloxacin ophthalmic solution 0.5% with a Paragraph IV certification.

ANSWER: Apotex admits that it filed ANDA No. 203523 for gatifloxacin ophthalmic solution 0.5%, which contains a Paragraph IV certification. Apotex denies all remaining allegations set forth in paragraph 23.

32. Upon information and belief, ANDA No. 203523 refers to, and relies upon, Allergan's NDA No. 22-548 and contains data that, according to Defendants, demonstrates the bioequivalence of the Defendants' proposed ANDA product to Allergan's Zymaxid® which is the subject of NDA No. 22-548.

ANSWER: Apotex admits that NDA No. 22-548 is identified in ANDA No. 203523 as the reference listed drug. Apotex denies all remaining allegations set forth in paragraph 32.

33. In a letter dated January 13, 2012, Apotex advised Plaintiffs that it had filed ANDA No. 203523 for gatifloxacin ophthalmic solution 0.5% which is the subject of Allergan's NDA. Allergan received that letter on January 16, 2012.

ANSWER: Apotex admits that Apotex transmitted a letter dated January 13, 2012 to Senju, Kyorin and Allergan. Apotex refers Plaintiffs to the referenced letter for its explicit terms. To the extent Plaintiffs' characterizations differ from the actual terms of the referenced letter, they are denied. Apotex denies knowledge or information sufficient to form a belief as to the remaining averments of paragraph 30 and therefore denies them.

34. The January 13, 2012 letter purports to advise Plaintiffs pursuant to 21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. §314.95 that Apotex's ANDA No. 203523 had been filed with a Paragraph IV certification to obtain approval to market a gatifloxacin ophthalmic solution 0.5% before the expiration of either the '045 Patent or U.S. Patent 5,880,283 (the '283 patent).

ANSWER: Apotex admits that Apotex transmitted a letter dated January 13, 2012 to Senju, Kyorin and Allergan. Apotex refers Plaintiffs to the referenced letter for its explicit terms. To the extent Plaintiffs' characterizations differ from the actual terms of the referenced letter, they are denied.

35. The January 13, 2012 letter does not state where the product of ANDA No. 203523 is to be manufactured and/or formulated.

ANSWER: Apotex admits that Apotex transmitted a letter dated January 13, 2012 to Senju, Kyorin and Allergan. Apotex refers Plaintiffs to the referenced letter for its explicit terms. To the extent Plaintiffs' characterizations differ from the actual terms of the referenced letter, they are denied.

36. Upon information and belief, Apotex manufactured and continues to manufacture, at least some, gatifloxacin sesquihydrate.

ANSWER: Apotex denies all allegations set forth in paragraph 36.

37. Upon information and belief, Apotex's gatifloxacin API contains at least some gatifloxacin sesquihydrate.

ANSWER: Apotex denies all allegations set forth in paragraph 37.

COUNT 1

Infringement of Claims 6-7, 12, and 14-16

38. Paragraphs 1-38 are incorporated herein as set forth above.

ANSWER: Apotex repeats and reasserts its responses set forth in paragraphs 1-37 as if set forth herein in full.

39. Apotex's submission of ANDA No. 203523 to obtain FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of gatifloxacin ophthalmic solution 0.5% in the United States before the expiration of the '045 Patent is an act of infringement of Claim 7 of the '045 Patent and Claims 6, 12 and 14-16 set forth on the '045 Patent reexamination certificate under 35 U.S.C. § 271(e)(2)(A).

ANSWER: The averments of paragraph 39 set forth conclusions of law to which no response or pleading is required. To the extent that such averments require a response, those averments are denied.

40. Defendants are jointly and severally liable for infringement of those claims.

ANSWER: Apotex denies all allegations set forth in paragraph 40.

41. Apotex's participation in the submission of ANDA No. 203523 and its

§505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Apotex denies all allegations set forth in paragraph 41.

42. Upon information and belief, Defendants were aware of the existence of the '045 Patent and the '045 Patent reexamination certificate and were aware that the filing of ANDA No. 203523 and certification with respect to the '045 Patent and the '045 Patent reexamination certificate constituted infringement. This is an exceptional case.

ANSWER: Apotex admits that it was aware of the '045 patent and reexamination certificate at the time that ANDA No. 203523 was filed. Apotex denies all remaining allegations set forth in paragraph 42.

COUNT 2

Infringement of Claim 1 of the '283 Patent

43. Paragraphs 1-43 are incorporated as set forth herein.

ANSWER: Apotex repeats and reasserts its responses set forth in paragraphs 1-43 as if set forth herein in full.

44. Apotex's submission of ANDA No. 203523 to obtain FDA approval to engage in the commercial manufacture, importation, sale, offer for sale, or use of gatifloxacin ophthalmic solution, 0.5% in the United States before the expiration of the '283 Patent was an act of infringement of Claim 1 under 35 U.S.C. 271(e)(2)(A) of the '283 Patent.

ANSWER: The averments of paragraph 44 set forth conclusions of law to which no response or pleading is required. To the extent that such averments require a response, those averments are denied.

45. Defendants are jointly and severally liable for infringement of the '283 Patent.

ANSWER: Apotex denies all allegations set forth in paragraph 45.

46. Apotex's participation in the submission of ANDA No. 203523 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '283 Patent under 35 U. S .0 . §271(e)(2)(A).

ANSWER: Apotex denies all allegations set forth in paragraph 46.

47. Upon information and belief, Defendants were aware of the existence of the '283 Patent and were aware that the filing of ANDA No. 203523 and certification with respect to the '283 Patent constituted infringement of that patent. This is an exceptional case.

ANSWER: Apotex admits it was aware of the '283 patent at the time that ANDA No. 203523 was filed. Apotex denies all remaining allegations set forth in paragraph 47.

PRAYER FOR RELIEF

ANSWER: Apotex specifically denies that Plaintiffs are entitled to the general or specific relief requested against Apotex, or to any relief whatsoever, and prays for judgment in favor of Apotex dismissing this action with prejudice, and awarding Apotex its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Apotex, Inc. and Apotex Corp. (collectively

"Apotex") aver and assert the following Affirmative Defenses to Plaintiffs', Senju Pharmaceutical Co., Ltd., Kyorin Pharmaceutical Co., Ltd. and Allergan, Inc.'s Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 6,333,045)

The manufacture, use, sale, offer to sell or importation into the United States of Apotex's proposed gatifloxacin ophthalmic solution that is the subject matter of ANDA No. 203523 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of U.S. Patent No. 6,333,045 ("the '045 patent") either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 6,333,045)

Upon information and belief, the claims of the '045 patent are invalid and/or unenforceable for failure to comply with one or more of the provisions of Title 35 of the United states Code, including, but not limited to Sections 101, 102, 103 and/or 112, and/or 37 CFR § 1.56.

THIRD AFFIRMATIVE DEFENSE
(Dismissal of Count II)

On February 14, 2012 the Court entered the parties' stipulation dismissing Count II of Plaintiffs' Complaint with prejudice.

FOURTH AFFIRMATIVE DEFENSE
(Unenforceability of U.S. Patent No. 6,333,045)

For the reasons stated in Count III of Apotex's Counterclaims below, the '045 patent is unenforceable due to inequitable conduct committed during its reexamination with unclean hands including, without limitation, the failure of the applicants, inventors, and/or those involved

in the reexamination, with intent to deceive the USPTO, to disclose prior art and information that was material to the reexamination of the '045 patent.

COUNTERCLAIMS

1. Counterclaimant Apotex Corp. is a corporation organized under the laws of the State of Delaware, and its principal place of business is located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

2. Counterclaimant Apotex, Inc. is a corporation organized under the laws of Canada, and its principal place of business is located at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

3. Upon information and belief, Counterclaim Defendant Senju Pharmaceutical Co., Ltd. ("Senju") is a corporation organized and existing under the laws of Japan having a place of business at 2-5-8, Hirano-Machi, Chuo-ku, Osaka 541-0046, Japan.

4. Upon information and belief, Counterclaim Defendant Kyorin Pharmaceutical Co., Ltd. ("Kyorin") is a corporation organized under the laws of Japan having a place of business at 5, Kanda Surugadai 2-chome, Chiyoda-ku, Tokyo 101-8311, Japan.

5. Upon information and belief, Counterclaim Defendant Allergan, Inc. ("Allergan") is a Delaware corporation having a place of business at 2525 Dupont Drive, Irvine, California, 92612.

6. As a consequence of Plaintiffs/Counterclaim Defendants' complaint against Apotex Corp. there is now an existing, continuing actual controversy between Senju, Kyorin and Allergan and Apotex Corp., regarding the alleged infringement, validity and enforceability of U.S. Patent Nos. 6,333,045, ("the '045 patent") and 5,880,283 ("the '283 patent").

7. This Court has jurisdiction over the subject matter of these counterclaims pursuant to §§ 1331 and 1338 (a) of Title 28 of the U.S. Code because they involve substantial claims arising out of the United States Patent Act, 35 U.S.C. § 1, *et. seq*.

8. This Court may declare the rights and legal relation for the parties pursuant to §§ 2201 and 2202 of Title 28 of the U.S. Code and § 271 (e)(5) of Title 35 of the U.S. Code because Apotex Corp.'s counterclaims present an actual controversy within the Court's jurisdiction that the patents asserted by Plaintiffs/Counterclaim Defendants against Defendant/Counterclaim Plaintiff, Apotex Corp. are not infringed and/or are invalid.

9. Venue for these counterclaims is proper within this District in which Plaintiffs/Counterclaim Defendants' Complaint is pending.

COUNT I
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '045 PATENT

10. The manufacture, use, sale, offer to sell or importation into the United States of Apotex, Inc.'s or Apotex Corp.'s proposed gatifloxacin ophthalmic solution that is the subject of ANDA No. 203523 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '045 patent either literally or under the doctrine of equivalents.

COUNT II
DECLARATORY JUDGMENT OF PATENT INVALIDITY OF THE '045 PATENT

11. Upon information and belief, the claims of the '045 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to Sections 103 and/or 112. Further, upon information and belief, the claims of the '045 patent are invalid under the doctrine of res judicata in light of the Court's opinion in

Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al., 07-779 (D. Del.).

12. Claim 6 of the '045 patent is invalid as obvious under 35 U.S.C. § 103 over one or more of the following: Grass, et al., "Effects of Calcium, Chelating Agents on Corneal Permeability," *Investigative Ophthalmology & Visual Science* 26(1): 110-113 (1985) ("Grass I"); Grass, et al., "Mechanisms of Corneal Drug Penetration I: In vivo and In Vitro Kinetics," *J. Pharm Sci.* 77(1): 3-14 (1988) ("Grass II"); Rojanasakul, et al., "Mechanism of action of some penetrating enhancers in the cornea: Laser scanning confocal microscopic and electrophysiologic studies," *International Journal of Pharmaceutics* 66: 131-142 (1990) ("Rojanasakul I"); Rojanasakul, et al., "The cytoskeleton of the cornea and its role in tight junction permeability," *International Journal of Pharmaceutics* 68: 135-149 (1991) ("Rojanasakul II"); and/or Sasaki, et al., "Effect of Preservatives on Systemic Delivery of Insulin by Ocular Instillation in Rabbits," *J. Pharm. Pharmacol.,* 46: 871-875 (1994) ("Sasaki"); in view of U.S. Patent No. 4,980,470 ("the '470 patent") and U.S. Patent No. 4,551,456 ("the '456 patent") and, optionally, further in view of U.S. Patent No. 4,780,465 ("the '465 patent") and/or U.S. Patent No. 5,284,776 ("the '776 patent") and/or Griffith, "Improvement of the Color Stability of Parenteral Solutions of Papaverine Hydrochloride," *J. Pharm. Sci.* 56(9): 1197-98 (1967) ("Griffith").

13. Claims 12-16 of the '045 patent are invalid as obvious under 35 U.S.C. § 103 in view of the '470 patent in combination with the '456 patent and/or the '465 patent, and further in view of the '776 patent and/or Griffith.

14. Claim 6 is also invalid for failure to meet the written description requirement of 35 U.S.C. § 112 because the '045 patent's specification fails to describe a method for raising corneal permeability of an aqueous Gatifloxacin eye drop solution comprising Gatifloxacin or its

salt, having a pH of from about 5 to about 6 containing from about 0.3 to about 0.8 w/v% Gatifloxacin or its salt, which comprises incorporating about 0.01 w/v% disodium edetate into said Gatifloxacin eye drop solution. In fact, the '045 patent nowhere discloses a method of raising corneal permeability of a gatifloxacin solution having 0.01 w/v EDTA and a person of ordinary skill in the art reading the four corners of the patent specification at the relevant time would not have immediately apprehended that the applicants were in possession of the subject matter that is defined by amended claim 6 in the re-examination certificate. Thus, claim 6, as amended, violates the written description requirement of 35 U.S.C. §112, ¶1 and constitutes the addition of improper new matter under 35 U.S.C. § 132 that was not supported by the original patent specification of the '045 patent as of the relevant time.

COUNT III[1]
DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '045 PATENT

15. Counterclaimants Apotex, Inc. and Apotex Corp. (collectively "Apotex") incorporate by reference the allegations of paragraphs 1-13 of their Counterclaims, as though fully set forth herein.

16. The '045 patent and its claims are unenforceable due to inequitable conduct committed during its reexamination, as more fully set forth below.

17. Title 37 of the Code of Federal Regulations § 1.56 and the Manual for Patent Examining Procedure § 2000.01 *et seq.* impose a duty of candor and good faith on each individual associated with the filing and prosecution of a patent application before the United

[1] Count III of Defendants' amended counterclaims (Declaratory Judgment of Unenforceability of the '045 Patent) was originally pleaded as "Count V" of Defendants' counterclaims. Originally-pleaded Counts III and IV (Declaratory Judgment of Noninfringement and Patent Invalidity of the '283 Patent) are not being replead in Defendants' Amended Answer, Affirmative Defenses, and Counterclaims in light of the Court's Order dated February 14, 2013 entering the parties' stipulation dismissing the '283 patent from this Action (D.E. 48).

States Patent and Trademark Office ("USPTO"), including reexamination, which requires that he or she disclose to the USPTO all information that is material to the patentability of the application under examination. Breach of this duty of candor, good faith and honesty with an intent to deceive the USPTO constitutes inequitable conduct so as to render the affected patent(s) unenforceable.

18. Upon information and belief, the '045 patent is void, unenforceable and of no legal effect by reason of inequitable conduct on the part of the inventors thereof and/or those acting on their behalf before the USPTO. Senju, Kyorin, the inventors and/or those acting on their behalf committed acts of inequitable conduct by failing to disclose information material to the reexamination of their respective applications and/or by submitting false or misleading information material to the reexamination of the applications. Specifically, Senju, Kyorin, the inventors and/or those acting on their behalf made affirmative misrepresentations (namely, one or more of Naoko Kishida, Takajuki Sawada, Jacob Doughty, Richard Kelly, Stephen Baxter, Akihiro Yamazaki and Frank West) and omitted material information in an attempt to distinguish the subject matter claimed in the '045 patent and reexamination certificate for that patent from that disclosed in the prior art. All such acts were committed with an intent to deceive the USPTO.

Inequitable Conduct During Reexamination

19. On February 25, 2011, Senju and Kyorin filed an *ex parte* request for the reexamination of claims 1-3, 6, 8, and 9 of the '045 patent with the United States Patent and Trademark Office ("USPTO") seeking to amend the claims. At the time of the reexamination request, these six claims were subject to a judgment ruling them invalid as obvious.

20. As part of the reexamination request, Senju, and its in-house counsel, including one or more of Naoko Kishida, and Kyorin and its in-house counsel, including one or more of Takajuki Sawada, through their reexamination counsel, Oblon Spivak, and its attorneys Jacob Doughty, Richard Kelly, Stephen Baxter, Akihiro Yamazaki, and Frank West filed the trial opinion, excerpts of the trial record, and certain expert reports that were favorable to their position on reexamination.

21. As part of the prosecution of the '045 patent's reexamination, Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West had a duty of disclosure to the USPTO under 37 C.F.R. § 1.56 and the Manual for Patent Examining Procedure § 2000.01 *et seq.*

22. As a result of their participation in *Senju Pharmaceuticals Co., Ltd. et al. v. Apotex Inc. et al.*, 07-779 (D. Del.), Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West were in possession of the full trial and discovery record from that case and had the opportunity to disclose the entire trial and discovery record to the USPTO.

23. Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West did not file excerpts of the trial record and expert reports disclosing that Kyorin's researchers had been the first to make and test gatifloxacin ophthalmic formulations covered by the '045 patent claims, nor did they produce evidence which showed that the formulations as claimed by the '045 patent did not exhibit unexpected results, the existence of which could have supported patentability.

24. Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West also did not file the deposition testimony by their own expert conceding that preparing the aqueous liquid compositions containing 0.3 w/v% gatifloxacin and 0.01 w/v% disodium edetate would have been obvious based on the well-known use of disodium edetate to prevent coloration of aqueous

liquid drug formulations.

25. This withheld information was material to patentability and shows that the added reexamination claims of the ‘045 patent were invalid as a matter of law as obvious. Withheld information also shows that Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West made a material misrepresentation about the presence of a secondary consideration supporting obviousness—contemporaneous invention.

26. On information and belief, Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West withheld this material information with an intent to deceive the USPTO with respect to the patentability of the subject matter claimed in the ‘045 patent and reexamination certificate.

27. On information and belief, Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West withheld this invalidating and contradictory material information in an attempt to deceive and mislead the USPTO regarding the patentability of the amended claims.

28. On information and belief, Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West were aware that the written description did not support the added limitations of amended claim 6 and therefore intentionally omitted reference to the only discussion of corneal permeability in the ‘045 patent specification, Experiment 1, when providing the USPTO with the support in the written description for the amendments made to claim 6.

29. On information and belief, Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West withheld this material information with an intent to deceive and mislead the USPTO regarding the patentability of the amended and/or added claims.

30. Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West submitted new claims 12-16 in the reexamination to narrow the scope of the compositions that had been claimed

in claims 1-3 and 9, which were canceled.

31. On information and belief, Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West committed inequitable conduct by seeking new claims 12-16 (aqueous liquid compositions comprising gatifloxacin and disodium edetate) which as a matter of law are invalid in light of Senju and Kyorin's and/or their expert's concession in litigation that claim 8 (incorporating disodium edetate into a liquid aqueous gatifloxacin composition for the purpose of preventing coloration) is invalid.

32. Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West made a material omission by failing to disclose the Kyorin's researchers' prior invention of gatifloxacin ophthalmic formulations containing disodium edetate and sodium chloride.

33. On October 25, 2011, the USPTO issued a reexamination certificate determining that amended claim 6 and new claims 12-16 are patentable over the materials submitted by Senju and Kyorin in the reexamination. These claims read as follows:

> 6. A method for raising corneal permeability of an aqueous pharmaceutical Gatifloxacin eye drop solution comprising Gatifloxacin or its salt, having a pH from above 5 to about 6 containing from about 0.3 to about 0.8 w/v% Gatifloxacin or its salt which comprises incorporating about 0.01 w/v% disodium edetate into [eye drops containing Gatifloxacin or its salt] said Gatifloxacin eye drop solution.
>
> 12. An aqueous liquid pharmaceutical eye drop composition which comprises from about 0.3 to about 0.8 w/v% Gatifloxacin or its salt, about 0.01 w/v% disodium edetate, and wherein the aqueous liquid pharmaceutical composition has a pH from about 5 to about 6.
>
> 13. The aqueous liquid pharmaceutical eye drop composition according to claim 12, comprising about 0.3 w/v% Gatifloxacin or its salt.

> 14. The aqueous liquid pharmaceutical eye drop composition according to claim 12, comprising about 0.5 w/v% Gatifloxacin or its salt.
>
> 15. The aqueous liquid pharmaceutical eye drop composition according to claim 12, comprising at least one isotonic agent selected from the group consisting of sodium chloride, potassium chloride, glycerin, mannitol and glucose.
>
> 16. The aqueous liquid pharmaceutical eye drop composition according to claim 14, wherein the at least one isotonic agent is sodium chloride.

34. In the Examiner's Statement of Reasons for Patentability and/or Confirmation, the Examiner states that the prior art fails:

> to teach or reasonably suggest, alone or in combination…an aqueous liquid pharmaceutical eye drop composition that comprises the claimed amounts of gatifloxacin (from about 0.3 w/v% to about 0.8 w/v% gatifloxacin or its salt) and the incorporation of disodium edetate in the particular amounts that are recited in the claims (about 0.01[sic] w/v% disodium edetate) at a pH from about 5 to about 6 (**claim 12**).

35. The Examiner further suggested that claim 12 was patentable because Senju and Kyorin submitted evidence of a secondary consideration that favored patentability—unexpected results of increased corneal permeability for the claimed compositions, without evidence of other secondary considerations.

36. On information and belief, Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West made these material misrepresentations and omissions with an intent to deceive the USPTO as to the patentability of the reexamined claims.

37. But for Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West's material misrepresentations and omissions, the USPTO would not have reached these conclusions and the reexamined claims of the '045 patent would not have issued.

38. Kishida, Sawada, Doughty, Kelly, Baxter, Yamazaki and/or West's material

misrepresentations and omissions amounted to affirmative egregious misconduct in dealing with the USPTO.

PRAYER FOR RELIEF

WHEREFORE, Apotex, Inc. and Apotex Corp, respectfully request the Court to enter judgment against counterclaim defendants Senju, Kyorin, and Allergan as follows:

A. Declaring that Apotex, Inc.'s or Apotex Corp.'s proposed gatifloxacin ophthalmic solution that is the subject of ANDA No. 203523 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '045 patent either literally or under the doctrine of equivalents.

B. Declaring that U.S. Patent No. 6,333,045 is invalid for failure to comply with one or more provisions of 35 U.S.C. § 103 and/or 112.

C. Declaring that U.S. Patent No. 6,333,045 is unenforceable as a result of inequitable conduct and/or unclean hands committed during its reexamination before the USPTO.

D. Declaring that Apotex, Inc.'s or Apotex Corp.'s proposed gatifloxacin ophthalmic solution that is the subject of ANDA No. 203523 would not and will not directly, indirectly, contributorily and/or by inducement, infringe any validly construed claim of the '283 patent either literally or under the doctrine of equivalents.

E. Awarding Apotex Corp. its reasonable costs and attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285; and

F. Awarding all such other and further relief as this Court may deem just and proper.

Dated: March 1, 2013

Respectfully Submitted,

MURPHY & LANDON

/s/Francis J. Murphy
Francis J. Murphy, DE I.D. No. 223
1011 Centre Road, Suite 210
Wilmington, Delaware 19805
(302) 472-8103
(302) 472-8135 (fax)
fmurphy@msllaw.com

Of Counsel:
Alan B. Clement
LOCKE LORD LLP
885 Third Avenue, 26th Floor
New York, NY 10022
(212) 947-4700
(212) 947-1202
dgreene@lockelord.com
aclement@lockelord.com
schen@lockelord.com

Keith D. Parr
Scott B. Feder
David B. Abramowitz
Patrick C. Gallagher
LOCKE LORD LLP
111 South Wacker Dr.
Chicago, Illinois 60606
312-443-0700
312-443-0336 (fax)
kparr@lockelord.com
sfeder@lockelord.com
dabramowitz@lockelord.com
pgallagher@lockelord.com

Attorneys for Defendants
Apotex Corp.

CERTIFICATE OF SERVICE

The undersigned on oath states that foregoing DEFENDANTS' AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS was served on the following counsel by electronic filing with the Court's ECF system and by placing a true and correct copy in the U.S. Mail on this 1st day of March 2013.

Jack B. Blumenfeld
Maryellen Noreika
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Richard D. Kelly
William T. Enos
Stephen G. Baxter
Frank J. West
OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
1940 Duke Street
Alexandria, VA 22314
(703) 413-3000
rkelly@oblon.com
wenos@oblon.com
sbaxter@oblon.com
fwest@oblon.com

MURPHY & LANDON

/s/Francis J. Murphy
Francis J. Murphy, DE I.D. No. 223
1011 Centre Road, Suite 210
Wilmington, Delaware 19805
(302) 472-8103
(302) 472-8135 (fax)
fmurphy@msllaw.com

Attorneys for Defendants
Apotex Corp.